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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,621	04/10/2001	Moshe Flashner-Barak	1662/52202	7987

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EXAMINER	
PULLIAM, AMY E	

ART UNIT	PAPER NUMBER
1615	13

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/829,621	Applicant(s) FLASHNER-BARAK, MOSHE	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3,-9, 12-18, 20-22, 24-29, 32-37, 40-48, 50-52, 54-59, 62-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3,-9, 12-18, 20-22, 24-29, 32-37, 40-48, 50-52, 54-59, 62-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Amendment C, received by the Office September 4, 2003.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33, 35, 43, 54, 55, and 62-71 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of US Patent 6,569,459. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim in not patentably distinct from the reference claim(s) because the examined claim is either anticipated by , or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US Patent 6,569,459 are generic to all the claims of the current application. That is, the claims of US Patent 6,569,459

fall entirely within the scope of the claims of the instant application, or, in other words, the claims of the US Patent 6,569,459 are anticipated by the claims of the instant application.

More specifically, US Patent 6,569,459 teaches a method of administering paclitaxel comprising introducing a dose of paclitaxel, and an apoptosis inducing plasma protein. Claims 33, 35, 43, 54, 55, and 62-71 of the instant application claims a method for administration of an anti-tumor chemotherapeutic, paclitaxel, and an apoptosis inducing agent, a plasma protein. Although the claims of the instant invention teach the use of microspheres, the broad language of the US Patent does not prohibit the presence of microspheres.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3,-9, 12-18, 20-22, 24-29, 32-37, 40-48, 50-52, 54-59, and 62-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,277,391 to Seo *et al* in view of US Patent 5,916,596 to Desai *et al.*.

Seo *et al.* teach a composition and method for trating diseases and disorders of the prostate. More specifically , Seo *et al.* teach a microspheres formulation comprising microspheres suspended in a liquid (c 3, l 43-35). The therapeutically effective substance will be combined with a biodegradable polymer to form the microspheres (c 3, l 25-26). The active agent can be an anticancer agent (c 3, l 20), such as paclitaxel (c 9, l 33). The biodegradable polymer is a member selected from the group consisting of polylactic acid, polyglycolic acid, or poly(lactic-co-glycolic) acid (c 3, l 32-36). The microspheres are generally between 10 and 100 microns, and the active agent comprises 10-50% of the total microsphere mass. This reference is relied upon to show that paclitaxel is known in microsphere formulations, as is a method of making microspheres made of PGA, PLA or copolymers thereof. Seo *et al.* also teach a release rate which overlaps Applicant's claimed rate of release (see figures).

Seo *et al.* do not teach the use of human serum albumin in combination with the active agent, paclitaxel.

Desai *et al.* are relied upon to teach the combination of human serum albumin and paclitaxel. Specifically, Desai *et al.* teach that paclitaxel is an anticancer drug capable of binding to human serum albumin. Furthermore, Desai *et al.* teaches that albumin is the natural carrier of the drug in the blood stream (column 6, lines 26-36).

Additionally, Hegedus *et al.* teach an invention related to water soluble products and pharmaceutical formulations in solid or liquid form (abstract). More specifically, Hegedus *et al.*

teach that the compositions comprise an active agent with a low aqueous solubility and a substantially affinity to plasma proteins. The reference teaches either human serum albumin or immunoglobulin as the plasma protein and paclitaxel as the active agent (p 41, claim 10). Hegedus *et al.* also teach that the formulation can be in solid or liquid form (p 43, claim 21). The reference describes the process of making the formulation, which includes dissolving the active in a solvent, combining the solution with a solution of the plasma protein, removing the organic solvent and lyophilizing the solution or its concentrates (p 44-45, claim 25).

The above combination of references do not specifically teach Applicant's claimed amount of active agent. However, it is the position of the examiner that it is within the skill of the ordinary worker to vary the amount of active ingredient, based on the specific need, particularly, the size of the patient, the size of the tumor, the severity of the tumor, and the length of time the patient is to be treated. Absent evidence to the contrary, it is the position of the examiner that the particular amount of active agent does not render patentable distinction to the instant claims.

Therefore, Seo *et al.* teach the use of a suspension of microspheres to deliver paclitaxel to a patient in need thereof. Desai *et al.* and Hegedus *et al.* both teach that paclitaxel and human serum albumin are known to be combined in pharmaceutical formulations. Furthermore, Desai *et al.* provides the motivation for combining the teachings, in that albumin is the natural carrier of paclitaxel in the blood stream. One of ordinary skill in the art would have been motivated to combine the above teachings to provide a chemotherapeutic formulation which has the sustained release effects of a microsphere formulation, in combination with the beneficial effects of human

serum albumin. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
November 14, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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